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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,421	06/11/1999	JOHN FRANCIS GORDON	043601/0110	2286

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EXAMINER
BEX, PATRICIA K

ART UNIT	PAPER NUMBER
1743	18

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/284,421	GORDON, JOHN FRANCIS	
	Examiner	Art Unit	
	P. Kathryn Bex	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-155* is/are pending in the application.

4a) Of the above claim(s) *45-88,100-104 and 132-155* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-99 and 105-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 June 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on November 16, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/136,070 is acceptable and a CPA has been established. An action on the CPA follows.

2. The addition of claims 105-155 is acknowledged and has been entered into the record.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 45-71 and 77-78, drawn to a multi-well assay plate structure, classified in class 73, subclass 864.72.

II. Claims 72-76 and 146-150, drawn to an assay disc plate for use in conducting optical assays, classified in class 436, subclass 165.

III. Claims 79-88 and 100-104, drawn to a method for conducting a chemical or biochemical assay, classified in class 435, subclass 30.

IV. Claims 89-99 and 105-131, drawn to a hydrophobic multi-reaction site plate, classified in class 422, subclass 102.

V. Claims 132-135, drawn to an optically transparent disc for use with an optical reader with lens, classified in class 356, subclass 73.

VI. Claims 136-145 and 151-155, drawn to an optically transparent disc comprising digitally encoded address information, classified in class 369, subclass 112.01.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions as presently claimed in Group I to Group VI are deemed to be independent inventions. The wells being proportioned and dimensioned such that fluid, introduced via at least one opening, is held by surface tension within the wells feature of the claims of Group I are not required by the claims of Groups II-VI. Similarly, the disc for rotation about a central axis feature of the claims of Group II is not required by the claims of Group I and Groups III-VI. Additionally, the method providing a enclosed chamber having a plurality of wells and treating each well with a first and second reagent is not required by the claims of Groups I-II and IV-VI. The hydrophilic reaction sites and the hydrophobic lower surface of the assay plate features of the claims of Group IV is not required by the claims of Groups I-III or Groups V-VI. The optically transparent disc having a lens feature of the claims of Group V is not required by the claims of Groups I-IV or Group VI. The optically transparent disc digitally encoded address information feature of the claims of Group VI is not required by the claims of Groups I-V. None of the claims as presently written link together the inventions set forth in Groups I-VI.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for the others, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Guy Smith on January 16, 2002 a provisional election was made without traverse to prosecute the invention of Group IV, claims 89-99 and 105-131. Affirmation of this election must be made by applicant in replying to this Office

action. Claims 45-88,100-104, and 132-155 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "64" has been used to designate both "plate insert" and "assay plate", see page 13, last paragraph. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

9. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "one or more lenses" included or molded into the structure, as recited in claims 121-122, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

10. Claim 99 objected to because of the following informalities: Examiner recommends that "an" be removed from the claim for clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 108, 110, 117, 121-122 and 131 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 108, recites "wherein said surfaces are provide by respective upper and lower plates of an optical disc." The specification does not support an *optical disc*. The specification does disclose the assay structure is a disc which included upper and lower circular plates.

Claims 110 and 131, introduce the limitation wherein "the plate structure is provided with digitally encoded information". As pointed out in the previous Office Action, paper no. 14, the specification describes only the use of a *second embodiment* which depicts the multi-well assay plate in the form of a *disk* 32 provided with digitally encoded address information.

Claim 117, recite the structure arranged to receive one or more inserts. However, this new limitation is not believed to be adequately supported within the instant specification. The specification describes the use of a *third embodiment*, see Figure 4, which depicts the disc assay plate 54 having a plurality of disc sectors arranged to receive a sector insert, see page 6, line 33

and page 13, line 26- page 14 , line 10. No other embodiments are disclosed as capable of receiving one or more inserts.

Claims 121-122, introduces the limitation, the structure including *one or more lenses* to improve optical inspection of said surface locations. Claim 122 recite wherein said one or more lenses are *molded into* said structure. However, Examiner does not believe that the instant specification supports the optically transparent structure comprising one or more lenses molded therein.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 89-99, 108, 123-131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 89, line 7, the phase "sufficiently small" is a relative phase which renders the claim indefinite. The phase "sufficiently small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How "small" is sufficient? Same deficiency was found in claim 105, line5 and claim 123, line 6.

Claim 108, now recites "wherein the surfaces are provided by respective upper and lower plates of an optical disc." What *optical disc* is applicant referring to? For examination purposes, Examiner has interpreted this to mean simply a disc.

Claim 123, line 7, the phrase "such that" renders the claim indefinite because it is unclear how the sites are constructed to retain fluid.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
>
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

16. Claims 89-91, 96, 105-107, 109, 123-124 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox (USP 5,041,266).

Fox teaches a multi-well tray comprising; a first upper surface 40, a second lower surface 22 having a plurality of wells 25 disposed therein, the first and second surfaces defining a space there between (Fig. 6). Additionally, the wells are so constructed that the inner surface 32 of the bottom wall is hydrophilic and the upper surface is hydrophobic. The tray includes an inlet 44 which allows fluids to be introduced and withdrawn from the chamber via a fluid introducing device 50. (column 3, line 43- column 6, line 39, Figs. 6-7). Note: the spacing between the upper and lower surface nor the volume of the reaction sites have not been restricted to any range and it is believed that the prior art device would have been fully capable of performing the same function, i.e. facilitate flow by capillary action and wells being constructed such that when excess fluid is withdrawn through the opening some of the liquid is left within the well.

17. Claims 89, 93, 96, 105-109, 112,116, 123-124 are rejected under 35 U.S.C. 102(e) as being anticipated by Croteau *et al* (USP 5,700,655).

Croteau *et al* teach a multi-well assay disc plate 10 comprising; a lid, a second lower surface having a plurality of wells 12 disposed therein, the lid and second surface defining a chamber having an opening 24 which allows fluids to be introduced and withdrawn from the chamber. The plate is made from a hydrophobic material. Moreover, each well is adapted to hold an aliquot of liquid and is sized and shaped and formed of a suitable material to hold the aliquot with the well by surface tension. Additionally, the surface of the wells can be treated with a hydrophilic material to enhance the retention of the liquid in the wells (column 2, lines 43-45, column 4, line 52- column 6, line 60, Figs. 2A-4B).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 90-92, 94-95, 111, 113-115, 117, 125, 127-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Zanzucchi *et al* (USP 5,585,069).

Croteau *et al* as discussed previously, do not teach a plate structure which is divided into sectors such that the space between the upper and lower plates is subdivided to provide a plurality of spaces, each space provided with a fluid introduction opening and vent opening to enable independent access to each space. However, such a design is considered conventional in the art, see Zanzucchi *et al*. Zanzucchi *et al* do teach a disc structure 14 which is divided into modular sectors 48 comprising a loading channel 34 and wells 36, 40, 42, 44 and a vent 46. Additionally, Zanzucchi *et al* teach a loading system 30 which may house one or more capillary tubes 32. As the sample loading tube is inserted into the loading channel of a disc sector, a sealant which can be adhered to the edge of the capillary sample tube or the loading channel, seals the capillary tube to the channel (column 5, line 65- column 6, line 2, Figs. 1A-3). Such use of a plurality of modules allows a large number of tests to be performed in parallel (column 4, line 60-62).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the assay apparatus of Croteau *et al* the handle means, as taught by Zanzucchi *et al*, in order perform a large number of independent tests in parallel.

21. Claims 90-92, 98-99, 110-120, 125-129, 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Merkh *et al* (USP 5,281,540).

Croteau *et al* as discussed previously, do not teach a disc structure which is divided into removable sectors. The disc structure including digitally encoded address information provided

for optical inspection. Merkh *et al* do teach a disc structure 18 which is divided into sector inserts 80 comprising wells 84. The system of Merkh *et al* includes a liquid injecting device 31 which penetrates the self-sealing cover 90 of each sector at port 92 (column 10, lines 1-7). Merkh *et al* teach the sector insert having digitally encoded address information 94 for use with a device having an optical inspection means 316 (column 30, line 51- column 32, line 54, Figs.1-2, 4-5, 14). Moreover, Merkh *et al* teach sectors inserts and a disc which include lock 100, 102, 104 and key 93 portions to allow the sectors to be snap-fitted in the correct orientation and the disc comprising plurality of dividing walls 122.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the assay apparatus of Croteau *et al* the digitally encoded address information means, as taught by Merkh *et al*, in order allow the operator to easily access patient information corresponding to the particular assay sector (column 10, line 60- column 11, line 21).

22. Claims 97 and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Takase *et al* (EP 417 305 A1).

Croteau *et al* as discussed previously, do not teach wherein either of the upper or lower plates includes a reflecting surface. Takase *et al* teach a liquid sample analyzer. The analyzer comprising a disc 101 with wells 104 and liquid sample supply means 9 for supplying liquid sample to the wells. Additionally, the analyzer system comprises a measuring means for measuring the reaction product produced. The disc has information formats 101, i.e. digitally encoded information, needed for analysis. The formats can be processed via a reflection method in which a reflecting film 101b can be formed on the upper or lower plates. A reading head 19 is

arranged above and/or below the formats to provide the predetermined information (page 11-12, Fig. 8b).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included the within the disc of Croreau *et al*, with the reflective surface in order to provide a reliable and permanent means of storing information pertaining to the reaction disc.

23. Claims 121-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Ford (USP 4,722,598).

Croteau *et al* as discussed above, do not teach an assay plate including one or more lenses molded into the structure to improve the optical inspection of the surface locations. Ford does disclose a base and cover plate. The base plate includes shallow wells 4 for holding a biological sample. The base plate includes thin transparent bottom lens 7 that is integrally formed and which define the bottom of each sample well (column 3, lines 1-68, Figs. 1-8). Such use of a bottom lens avoids any optical distortion which might occur during microscopic observation of the sample contained in the various sample wells (column 3, lines 60-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included the within the assay plate of Croreau *et al*, the integrally molded lens, in order to avoid any optical distortion which might occur during microscopic observation of the sample contained in the various sample wells.

Response to Arguments

24. Applicant's arguments filed September 25, 2001 have been fully considered but they are not persuasive. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount

to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references, see page 7, paragraph 4 in the REMARKS section of the response.

Conclusion

25. No claims allowed.

26. The prior art made of record and not relied upon which is considered pertinent to applicant's disclose are Pierson *et al*, Brown *et al* and Bohannon *et al*. They are cited of interest in that they show microorganism culture trays.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 or (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703)872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

P. Kathryn Bex
Patent Examiner
AU 1743
1/23/02

JEFFREY SNAY
PRIMARY EXAMINER